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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/15/96 11/24/99 C. R. R. R.

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EXAMINER

SCHEIDT, M

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

11/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/978,635

Applicant(s)

Rabanni et al.

Examiner

Schmidt

Group Art Unit

1635

---The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address---

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 8/20/99

☒ This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 245-251 is/are pending in the application.

Of the above claim(s) is/are withdrawn from consideration.

Claim(s) is/are allowed.

☒ Claim(s) 245-251 is/are rejected.

Claim(s) is/are objected to.

Claim(s) are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number)

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s).

Interview Summary, PTO-413

Notice of References Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other

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DETAILED ACTION

Double Patenting

1. Claims 245-247 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 255, 257 and 259 of copending Application No. 08/978,636. Although the conflicting claims are not identical, they are not patentably distinct for the same reasons of record as stated in the first Official action mailed 02/16/99.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Examiner acknowledges the Applicant's intention to await until any subject matter is deemed allowable in either or both applications before further addressing the double patenting rejection over instant claims 245-247.

Claim Rejections - 35 USC § 112

2. Claims 245-251 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the same reasons of record set forth in the Official action mailed 02/16/99.

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Applicant's arguments filed 08/20/99 have been fully considered but they are not persuasive.

Applicant argues for enablement of the prophetically taught multicassette constructs, having A, B, C and T7 polymerase, by asserting that no undue experimentation would be necessary to make and use such constructs.

However, as was argued in the first Official action on the merits, the instant claims read on a multitude of constructs for application in a cell or whole organism, including for instance application of antisense constructs to a cell, but the specification as filed is not enabling for the breadth of constructs claimed, including the prophetically taught multicassette constructs.

The specification as filed taught prophetically how to make and use a variety of nucleic acid constructs and taught by way of example a vector construct for administration of antisense molecules to cells in culture. It was then argued that the constructs taught either prophetically or by way of example which read on expressing an antisense construct *in vitro*, would not be enabled for application to a whole organism because of the unpredictability in the antisense art for whole organism administration of such constructs.

Applicant made no attempt to refute the unpredictability of administration of antisense expressing constructs to whole organisms, including the multicassette constructs. No remarks were presented addressing the factors which contribute to the unpredictability of whole organism application of the instantly claimed constructs, especially in view of the lack of teaching in the specification and the art for constructs encompassed by the breadth of the claimed invention

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having the claimed functionality of producing a product in a cell in a whole organism. The rejection thus stands for lack of teaching in the specification as filed for one skilled in the art to make and/or use the instantly claimed constructs since mere assertion that the ordinarily skilled artisan, armed with the disclosure could make and use the claimed invention, does not constitute evidence to overcome the *prima facie* case of enablement.

Claim Rejections - 35 USC § 102

3. Claims 245-251 are rejected under 35 U.S.C. 102(e) as being anticipated by Sullenger et al., for the same reasons of record set forth in the Official action mailed 02/16/99.

Applicant's arguments filed 08/20/99 have been fully considered but they are not persuasive.

Applicant responds that Sullenger et al.'s patent does not anticipate Applicant's invention due to a lack of identity of material elements. Applicant does not explain how the elements taught by Sullenger et al. are not material to the instant invention as broadly claimed.

4. Claims 245-251 are rejected under 35 U.S.C. 102(b) as being anticipated by De Young et al., for the same reasons of record set forth in the Official action mailed 02/16/99.

Applicant's arguments filed 08/20/99 have been fully considered but they are not persuasive.

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Applicant responds that De Young et al.'s patent does not anticipate Applicant's invention. Applicant does not provide any supporting evidence as to how the invention taught by De Young et al. fails to disclose the instant invention as broadly claimed.

5. Claims 245-251 are rejected under 35 U.S.C. 102(e) as being anticipated by Hurwitz et al., for the same reasons of record set forth in the Official action mailed 02/16/99.

Applicant's arguments filed 08/20/99 have been fully considered but they are not persuasive.

Applicant responds that Hurwitz et al.'s patent does not disclose nor suggest Applicant's invention. Applicant does not provide any supporting evidence as to how the invention taught by Hurwitz et al. neither discloses nor suggests the instant invention as broadly claimed.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *George Elliott, Ph.D.* may be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



M. M. Schmidt
November 22, 1999

George C. Elliott
Supervisor
Art Unit 1635
November 22, 1999